Quality Matters

Implementation of a Quality Management System for the Regulatory Processes of a National Regulatory Authority

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Discussion Overview

- What is quality for a National Regulatory Authority like CDRH?
- The CDRH Quality Management System (QMS)
- Reflections

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What is quality for a National Regulatory Authority like CDRH?

For CDRH, it's adherence to ISO:9001

Quality management principles (iso.org)

Quality Management (QM)

- Managing activities and resources of an organization to achieve objectives and prevent nonconformances

Quality Management System (QMS)*

- A formal system that documents the structure, processes, roles, responsibilities and procedures required to achieve effective quality management.
- A QMS helps coordinate and direct an organization's activities to meet customer and regulatory requirements and improve its effectiveness and efficiency on a continuous basis.
- ISO 9001:2015, the international standard specifying requirements for quality management systems, is the most prominent approach to quality management systems. While some use the term "QMS" to describe the ISO 9001 standard or the group of documents detailing the QMS, it actually refers to the entirety of the system. The documents only serve to describe the system.

*What is a Quality Management System (QMS)? | ASQ

What is quality for a National Regulatory Authority like CDRH?

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Quality management principles (iso.org)

Purpose

- ISO:9001 is a standard used by organizations to demonstrate their ability to consistently provide products and services that meet customer and regulatory requirements and to demonstrate continuous improvement

Context

- ISO:9001 is the International Standard for a QMS
- ISO:9001 is a certification that certain formal processes are being used within a company for their management of Quality Control
- ISO:9001 is based on the **Plan-Do-Check-Act** methodology and provides a process-oriented approach to documenting and reviewing the structure, responsibilities, and procedures required to achieve effective quality management in an organization

What is quality for a National Regulatory Authority like CDRH?

Quality at CDRH means ensuring patients and providers have timely and continued access to safe, effective, and high-quality medical devices and radiation emitting products

Key Tenets of CDRH quality include

- **Transparency, standardization, predictability,** and **simplicity** are themes CDRH uses to serve their customers and stakeholders
- **Customer focus** allows CDRH to understand customer needs and seek opportunities for improving CDRH products and services that foster **continuous improvement** efforts

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The CDRH Quality Management System (QMS)

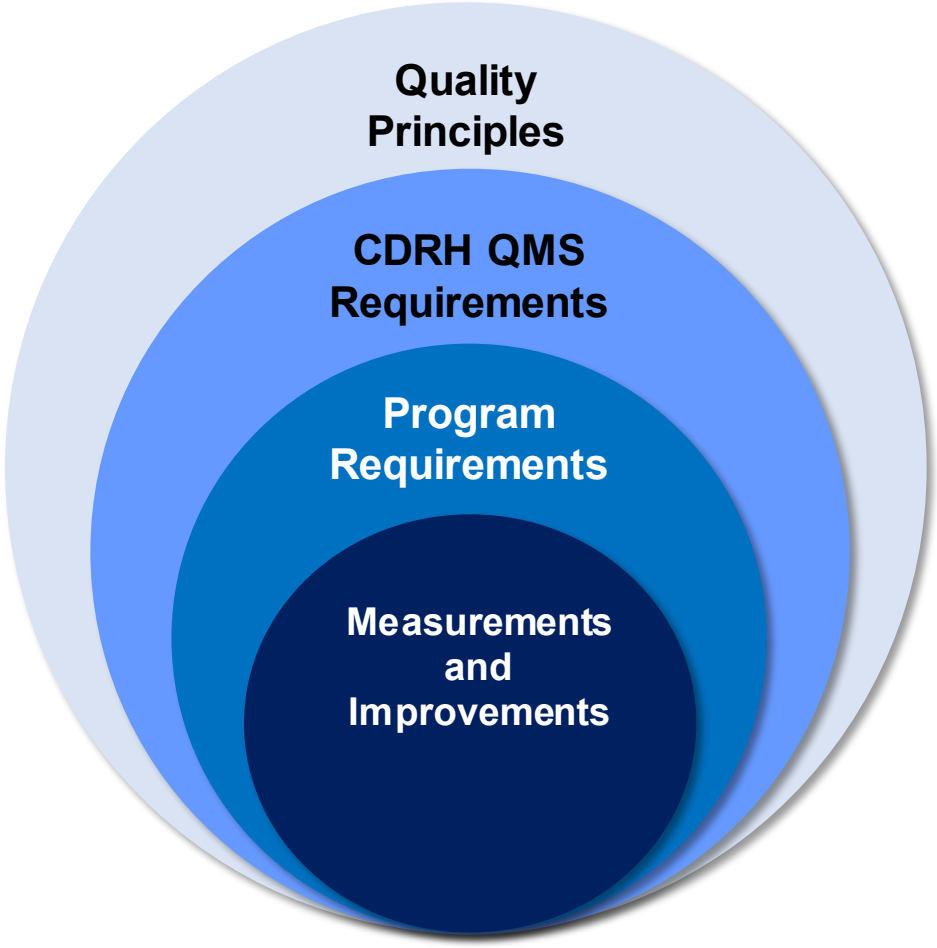
High-level overview of what can be managed through the CDRH QMS

Quality Principles

- Continuous Process Improvement (CPI)
- ISO:9001 Standards
- CDRH Quality Policy
- CDRH Program Framework
- CDRH Mission and Vision

Program Requirements

- Does the program have the clearly documented technical requirements?
- How does the program show the technical requirements?
- Does the program have the clearly documented business requirements?
- Is there evidence of use of documented processes and improvements?



CDRH QMS Requirements

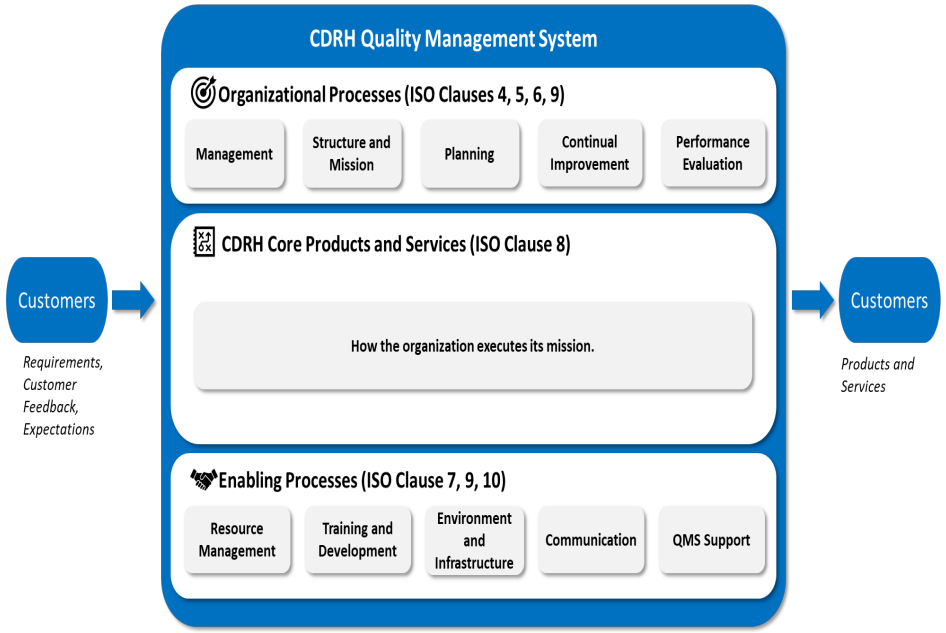
- Adherence to one Center-level QMS and action activities that are traceable and based on data/customer input
- Uses document control and incorporates customer feedback
- Uses process improvement and manages nonconformities
- Has an Internal Audit Program
- Uses and incorporates Risk Management
- Determines, provides, and documents required training and capabilities
- Manages records

Measurements and Improvements

- Does the program have clear, attainable and measurable metrics to track process performance?
- Are improvement activities justifiable—data, ideas, customer input?

The CDRH Quality Management System (QMS)

A formal system that documents processes, procedures, and responsibilities for achieving quality policies and objectives



Purpose

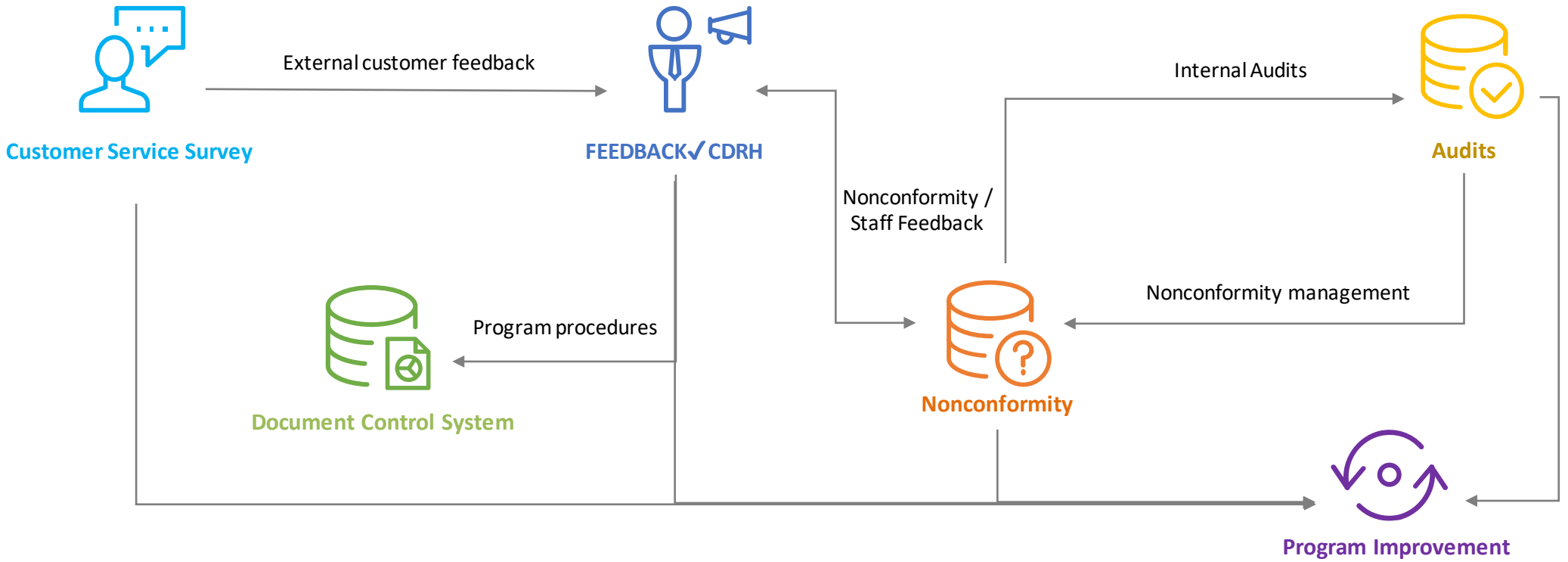
- The CDRH QMS is essential to the management and improvement of CDRH core processes, which supports our Center's public health mission
- CDRH is committed to delivering high-quality products and services to its customers in pursuit of achieving its Mission and Vision

Context

- CDRH established a QMS—a formal system used to review operations, products and services, and identify areas that may require quality improvements
- The CDRH QMS supports and enhances the Center's programs, products and services
- The CDRH QMS complies with the ISO:9001 Standard and has been successfully certified to ISO 9001:2015 since 2018

The CDRH Quality Management System (QMS)

Managing Quality with the CDRH QMS Infrastructure



- The CDRH QMS infrastructure supports the Center QMS and **ISO:9001 compliance.**
- QMS processes bring a level of **rigor and standardization** for programs across the Center

Managing Quality with the CDRH QMS Infrastructure

Voice of the Customer

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Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: https://www.research.net/s/cdrhcustomerservice?ID=2010&S=E

Feedback mechanisms help assess effectiveness, customer satisfaction, and drive improvements

- **FEEDBACK✓CDRH** is a One Stop Shop for staff to submit ideas, suggestions and issues.
- The **CDRH Customer Service Survey** is available to external and internal customers. All CDRH staff must have a link to the **CDRH Customer Service Survey** in their signature block

Managing Quality with the CDRH QMS Infrastructure

Documented Information

Programs use the **CDRH Document Control System (DCS)** to document their structure, processes, roles, responsibilities and procedures

- The **CDRH DCS** stores and makes available all QMS documentation to CDRH
- The **CDRH DCS** supports consistency and standardization by housing all CDRH's mission critical procedures in one central repository

In addition, programs use established **record management** guidelines to manage important information that must be kept organized and controlled

Managing Quality with the CDRH QMS Infrastructure

Continual Improvement

Programs determine whether their processes are in control using the **Audit** system and **Quality Management Reviews**

- Input from staff and customers as well as results from **Audits** may identify a **Nonconformity**
- Programs use **Program Improvement** to determine capabilities, design processes, and set metrics that foster improvement and standardization

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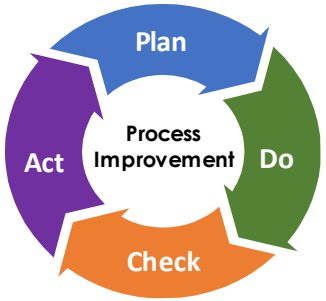

Reflections

The CDRH QMS follows a "Plan, Do, Check, Act" methodology

1. Understand Customer requirements
   - ✓ Collect feedback
2. Document Information
   - ✓ Oversee procedures and quality policy
3. Record Keeping
   - ✓ Keep evidence of what matters
4. Track Performance
   - ✓ Monitor for signals
5. Internal Audits
   - ✓ Ensure conformity and identify improvement opportunities
6. Management Reviews
   - ✓ Strategic review of activities and resources
7. Correct
   - ✓ Address problems
8. Program Improvement
   - ✓ Improve program and program procedures

Thank You!

Excellence, then, is not an act but a habit. |Questions?

Will Durant